

## PATENT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents  
United States Patent and Trademark  
Office  
Box PCT  
Washington, D.C.20231  
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year)  
02 August 2000 (02.08.00)

International application No.  
PCT/US99/22940

Applicant's or agent's file reference  
SOM010329APC

International filing date (day/month/year)  
13 October 1999 (13.10.99)

Priority date (day/month/year)  
13 October 1998 (13.10.98)

## Applicant

BARRETT, Bruce, J. et al

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:  
28 April 2000 (28.04.00)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was  
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

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Authorized officer

Pascal Piriou

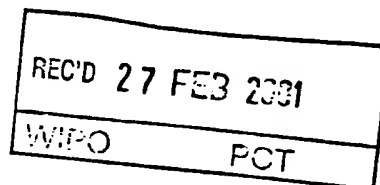
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## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference SOMO10329APC	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US99/22940	International filing date (day/month/year) 13 OCTOBER 1999	Priority date (day/month/year) 13 OCTOBER 1998
International Patent Classification (IPC) or national classification and IPC IPC(7): A61B 5/00 and US Cl.: 600/323		
Applicant SOMANETICS CORPORATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 10 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 28 APRIL 2000	Date of completion of this report 23 JANUARY 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer  JOSEPH CADOGAN
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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/22940

**I. Basis of the report**

## 1. With regard to the elements of the international application:\*

- ☐ the international application as originally filed
- ☒ the description:  
pages (See Attached) \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the claims:  
pages (See Attached) \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, as amended (together with any statement) under Article 19  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the drawings:  
pages (See Attached) \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the sequence listing part of the description:  
pages (See Attached) \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.  
These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/fig NONE

5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\*Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/22940

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. statement

Novelty (N)

Claims 1-62 YES  
Claims NONE NO

Inventive Step (IS)

Claims 1-62 YES  
Claims NONE NO

Industrial Applicability (IA)

Claims 1-62 YES  
Claims NONE NO

### 2. citations and explanations (Rule 70.7)

Claims 1-62 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest the simultaneous and continuous spectrophotometric examination, computation and comparative display of blood constituent levels in different areas of the brain.

----- NEW CITATIONS -----  
NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JS99/22940

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

**I. BASIS OF REPORT:**

This report has been drawn on the basis of the description,  
page(s) 1-13, as originally filed.  
page(s) NONE, filed with the demand.  
and additional amendments:  
NONE

This report has been drawn on the basis of the claims,  
page(s) 14-22, as originally filed.  
page(s) NONE, as amended under Article 19.  
page(s) NONE, filed with the demand.  
and additional amendments:  
Pages 14-22a, filed with the letter of 17 November 2000.

This report has been drawn on the basis of the drawings,  
page(s) 1-5, as originally filed.  
page(s) NONE, filed with the demand.  
and additional amendments:  
NONE

This report has been drawn on the basis of the sequence listing part of the description:  
page(s) NONE, as originally filed.  
pages(s) NONE, filed with the demand.  
and additional amendments:  
NONE

The invention claimed is:

1. A method for spectrophotometric in vivo monitoring of blood metabolites in a plurality of different regions on an ongoing and substantially instantaneous basis, comprising the steps of:

5 applying a plurality of spectrophotometric sensors to a test subject at each of a corresponding plurality of testing sites and coupling each such sensor to a control and processing station;

operating certain of said sensors to spectrophotometrically irradiate a particular region within the test subject associated certain each such testing sites;

10 detecting and receiving the light energy resulting from said spectrophotometric irradiation for certain such particular regions, and conveying signals to said control and processing station which correspond to the light energy so received;

analyzing said conveyed signals to determine preselected blood metabolite data representative of at least two such regions; and

15 visually displaying said data for each of said at least two regions for direct mutual comparison.

2. The method of claim 1, wherein said step of analyzing comprises determination of blood oxygenation state within each of said at least two regions.

20 3. The method of claim 2, wherein said analyzing determination includes producing a quantitative value designation for hemoglobin oxygen saturation for each of at least two said regions.

25 4. The method of claim 3, wherein said analyzing determination includes production of an ongoing graphical trace representing a plurality of said quantitative value designations made at successive points in time.

30 5. The method of claim 3 including the step of visually displaying a plurality of said quantitative value designations at substantially the same time and in predetermined relationship to one another to facilitate rapid and accurate visual comparison.

6. The method of claim 4 including the step of visually displaying a plurality of said graphical traces at substantially the same time and in predetermined relationship to one another to facilitate rapid and accurate visual comparison.

5 7. The method of claim 6 including the step of visually displaying a plurality of said quantitative value designations as well as said graphical traces at substantially the same time and in predetermined relationship to one another to facilitate rapid and accurate visual comparison.

10 8. The method of claim 1, including the step of providing signals to said control and processing station which comprise at least two data sets that cooperatively define blood metabolite data for an individual one of said particular regions.

15 9. The method of claim 1, wherein said sensors are applied to the head of the test subject and used to monitor the brain.

10. The method of claim 9, wherein said metabolite comprises hemoglobin oxygen.

20 11. The method of claim 9, wherein said sensors are positioned in locations proximate to different brain hemispheres and used to separately monitor each such hemisphere.

25 12. The method of claim 11, wherein said metabolite comprises cerebral blood hemoglobin oxygenation.

13. The method of claim 11, including the step of providing signals to said control and processing station which comprise at least two data sets which cooperatively define blood metabolite data for an individual one of said particular regions.

30 14. The method of claim 8, wherein said provided data sets include one such set which characterizes a first zone adjacent said particular region and another such set which characterizes a second zone that is at least partially within said particular region.

15. The method of claim 14, wherein said second zone characterized by said other such data set includes at least part of said first zone.

16. The method of claim 1, wherein said sensors are applied to the outside periphery of the test subject and operate non-invasively.

17. Apparatus for spectrophotometric in vivo monitoring of blood metabolites in each of a plurality of different regions on a substantially concurrent basis, comprising:

a plurality of spectrophotometric sensors, each attachable to a test subject at different test locations and adapted to spectrophotometrically irradiate a given region within the test subject associated with such test location;

a controller and processor, and circuitry coupling each such sensor to said controller and processor for individually operating certain of said sensors to spectrophotometrically irradiate a given region within the test subject associated with each such test location;

said sensors each further adapted to receive light energy resulting from the spectrophotometric irradiation produced by that sensor for said region, and to produce corresponding signals; and said circuitry acting to convey said signals to said controller and processor for analytic processing;

said controller and processor adapted to analytically process said conveyed signals and thereby determine preselected blood metabolite data therefrom; and

a visual display coupled to said controller and processor and adapted to display the metabolite data so determined for each of a plurality of regions in a mutually-comparative manner.

18. The apparatus of claim 17, wherein said controller and processor is adapted to analyze said data to determine the blood oxygenation state within at least two of said regions

19. The apparatus of claim 18, wherein said controller and processor is adapted to produce numeric value designations for hemoglobin oxygen saturation for at least two of said regions.



20. The apparatus of claim 19, wherein said controller and processor and said display are adapted to produce an ongoing graphical trace representing a plurality of said numeric value designations taken over a period of time.

5 21. The apparatus of claim 19 wherein said controller and processor and said display are adapted to visually display at least two of said numeric value designations on a substantially concurrent basis and in predetermined relationship to one another to facilitate rapid and accurate visual comparison.

10 22. The apparatus of claim 20 wherein said controller and processor and said display are adapted to visually display at least two of said graphical traces on a substantially concurrent basis and in predetermined relationship to one another to facilitate rapid and accurate visual comparison.

15 23. The apparatus of claim 22 wherein said controller and processor and said display are adapted to visually display at least two of said numeric value designations as well as at least two of said graphical traces on a substantially concurrent basis and in proximity to one another to facilitate rapid and accurate visual comparison.

20 24. The apparatus of claim 17, wherein said sensors are adapted to provide signals to said controller and processor which comprise at least two data sets that cooperatively define at least portions of each of said given regions.

25 25. The apparatus of claim 17, wherein said sensors are adapted to be applied to the head of a test subject and to monitor its brain.

26. The apparatus of claim 25, wherein said computer is adapted to determine blood oxygenation saturation in said brain.

30 27. The apparatus of claim 25, wherein said sensors are adapted to be positioned in locations associated with different brain hemispheres and are operable to separately monitor at least portions of each such hemisphere.

28. The apparatus of claim 27, wherein said controller and processor is adapted to determine cerebral blood oxygenation saturation within said hemispheres.

29. The apparatus of claim 27, wherein said sensors are adapted to provide signals to said controller and processor which comprise at least two data sets that cooperatively define at least portions of each of said regions.

30. The apparatus of claim 24, wherein said data sets provided by said sensors include one such set characterizing a first zone adjacent said given region and another such set characterizing a second zone at least partially within said given region.

31. The apparatus of claim 30, wherein said second zone characterized by said other such data set includes at least part of said first zone.

32. The apparatus of claim 17, wherein said sensors are adapted to be applied to the outside periphery of the test subject and to operate non-invasively.

33. A method for comparative in vivo monitoring of blood metabolites in each of a plurality of different regions, comprising the steps of:

spectrophotometrically irradiating each of a plurality of different testing sites on a test subject;

detecting light energy resulting from said spectrophotometric irradiation for a plurality of such testing sites, and providing signals to a control and processing station which are representative of the light energy so received for said plurality of testing sites;

analyzing said conveyed signals to determine preselected blood metabolite data representative of at least one particular region within the test subject associated with each of at least two of said plurality of testing sites, each such region being different from the other; and

displaying said data for each of said at least two regions for direct mutual comparison.

34. The method of claim 33, wherein the step of providing signals to said control and processing station comprises providing at least two data sets that cooperatively define blood metabolite data for an individual one of said particular regions.

5 35. The method of claim 34, wherein said provided data sets include one such set which characterizes a first zone adjacent said particular region and another such set which characterizes a second zone that is at least partially within said particular region.

10 36. The method of claim 35, wherein said second zone characterized by said other such data set includes at least part of said first zone.

15 37. The method of claim 33, wherein said step of spectrophotometrically irradiating is carried out by using sensors applied to the outside periphery of the test subject and operated non-invasively.

38. The method of claim 33, wherein said control and processing station is used to time and sequence emission of spectrophotometric radiation at said testing sites and detection of resulting light energy at said sites.

20 39. The method of claim 33, wherein said spectrophotometric irradiation of said testing sites is done sequentially and alternatively.

25 40. The method of claim 33, wherein said spectrophotometric irradiation comprises application of at least two different wavelengths, and such wavelengths are applied in an alternating sequence of timed pulses.

41. The method of claim 40, including detection of the resulting light energy corresponding to each of said wavelengths on a timed periodic basis using periods whose occurrence corresponding to that of said applied spectrophotometric wavelength pulses.

30 42. The method of claim 41, wherein the duration of each of said timed detection periods is limited to a length which is less than that of each pulse of applied spectrophotometric irradiation energy.

43. The method of claim 42, wherein the duration of each of said detection periods is less than half that of a pulse of said applied spectrophotometric irradiation.

5 44. The method of claim 43, wherein a plurality of said detection periods are used during pulses of said applied irradiation, and a corresponding energy detection occurs during each of a plurality of said detection periods.

10 45. The method of claim 44, further including the steps of averaging a selected number of energy detection event values to obtain a resultant value therefor, and using said resultant value to compute a metabolite value which is representative thereof.

15 46. The method of claim 45, wherein said display includes said computed representative metabolite value.

20 47. The method of claim 46, wherein said display is refreshed periodically by using a sequence of computed representative metabolite values which are based upon and represent the averaged detection event values produced during the different time intervals corresponding to the intervals of said periodic display refreshment.

25 48. Apparatus for spectrophotometric in vivo monitoring of a selected metabolic condition in each of a plurality of different test subject regions on a substantially concurrent basis, comprising:

a plurality of spectrophotometric emitters, each adapted to spectrophotometrically irradiate a given region within a test subject from a test location on a test subject;

a controller and processor, and circuitry coupling each such emitter to said controller and processor for individually operating selected such emitters to spectrophotometrically irradiate at least two regions within a test subject from at least one selected test location;

30 a plurality of detectors adapted to receive light energy resulting from the spectrophotometric irradiation of said at least two regions, and to produce corresponding signals; and circuitry acting to convey said signals to said controller and processor for analytic processing;

said controller and processor adapted to analytically process said conveyed signals to determine data representative of said metabolic condition in said at least two regions; and

5 a visual display coupled to said controller and processor and adapted to display representations of said metabolic data for said at least two regions in a mutually-comparative manner.

10 49. The apparatus of claim 48, wherein said controller and processor includes a computer programmed to analyze said detector signals to determine the blood oxygenation state within said at least two regions.

15 50. The apparatus of claim 49, wherein said computer comprises a processor, data buffers, and a timing signal generator, said data buffers adapted to store data representative of said blood oxygenation state and said timing signal generator adapted to control actuation of said emitters and detectors accordingly.

51. The apparatus of claim 49, wherein said controller and processor comprises a unitary device which includes said computer and said display.

20 52. The apparatus of claim 51 wherein said unitary controller and processor device further includes a keyboard interface to said computer.

25 53. The apparatus of claim 51 wherein said unitary controller and processor device further includes a data output interface.

54. The apparatus of claim 53 wherein said unitary controller and processor device further includes an integral keyboard interface to said computer.

30 55. The apparatus of claim 51, wherein said display comprises a flat electroluminescent visual display screen.

56. The apparatus of claim 55 wherein said unitary controller and processor unit further includes an integral keyboard interface to said computer.

57. The apparatus of claim 48, wherein at least certain of said detectors and certain of said emitters comprise operational pairs, and said controller and processor is arranged to operate the emitters and detectors of at least certain of such pairs in predetermined  
5 timed relationship while maintaining the emitters and detectors of other such pairs in a non-operating condition.

58. The apparatus of claim 57, wherein said controller and processor is adapted to sequence the operation of certain of such emitter-detector pairs.

59. The apparatus of claim 57, wherein at least certain of said operational emitter detector pairs include at least two detectors and at least one such detector is located nearer the emitter of such pair than at least one of the other detectors to provide near and far detector groupings for that operational pair.

60. The apparatus of claim 58, wherein at least certain of said operational pairs include a plurality of said detectors arranged at mutually spaced locations which are spaced at differing distances from the emitter of their operational pair.

61. The apparatus of claim 59, wherein said controller and processor is adapted to sequence the operation of certain of such emitter-detector pairs.

62. The apparatus of claim 60, wherein said controller and processor is adapted to operate the emitter and a selected number less than all of the detectors of at least one of  
25 said at least certain of said operational pairs substantially in unison while holding the other detectors of said at least one operational pair in non-operating condition, and said controller and processor is further arranged to operate such other detectors substantially in unison with said emitter at another time during which said selected number of detectors are maintained in a non-operating condition.

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US99/22940

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 5/00

US CL :600/323

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/310, 322, 323, 340, 473

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y,P	US 5,902,235 A (LEWIS et al.) 11 May 1999, entire document.	1-62
Y	US 5,482,034 A (LEWIS et al.) 09 January 1996, entire document.	1-62
Y,P	US 5,853,370 A (CHANCE et al.) 29 December 1998, entire document.	1-62
Y	US 5,803,909 A (MAKI et al.) 08 September 1998, entire document.	1-62
Y	US 4,910,404 A (CHO et al.) 20 March 1990, entire document.	1-62
Y	US 5,088,493 A (GIANNINI et al.) 18 February 1992, entire document.	1-62



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A* document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*E* earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*G* document member of the same patent family
*O* document referring to an oral disclosure, use, exhibition or other means	
*P* document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

27 JANUARY 2000

Date of mailing of the international search report

28 FEB 2000

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# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US99/22940

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,190,039 A (TAKEUCHI et al.) 02 March 1993, entire document.	1-62
Y	US 5,477,853 A (FARKUS et al.) 26 December 26, 1995, entire document.	1-62
Y	US 5,542,421 A (ERDMAN) 06 August 1996, entire document.	1-62
A	US 5,787,887 A (KLINGENBECK-REGN) 04 August 1998, entire document.	1-62
A,E	US 5,974,337 A (KAFFKA et al.) 26 October 1999, entire document.	1-62